K050195

MAR 17 2005

Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR part 807.92.

1. Company making the submission:

	Company
Name:	Gish Biomedical, Inc.
Address:	22942 Arroyo Vista Rancho Santa Margarita CA 92688-2600
Telephone:	949-635-6240 voice 949-635-6294 fax
Contact:	Edward F. Waddell Director RA/QA

2. Device:

Proprietary Name:	Circulatory Technology Inc. V-BAG™ with GBS® Coating.
Common Name:	Soft Venous Reservoir
Classification Name:	Reservoir, blood, cardiopulmonary bypass

3. Predicate Devices:

Circulatory Technology Inc. V-BAG™. K001822 and Gish Soft Venous Reservoir SVR with GBS™ Coating, K024065,

4. Classifications Names & Citations:

5. 21 CFR 870.4400, Reservoir, blood, cardiopulmonary bypass, Class II, DTN, Cardiovascular.

6. Description:

The V-BAG™ with GBS® Coating is an expandable blood chamber having a polyester screen with a pore size of 105μ separating the inlet from the outlet of the blood chamber. The inlet tube enters the blood chamber at its top and extends to the bottom of the screen. Blood flows from the inlet tube, across the screen, and to the outlet port. The screen, once wet, allows passage of liquid but rejects most air bubbles. Bubbles float up and are removed through the purge line. Channels formed along the outside diameter of the tubes placed vertically, running from the bottom of the inlet section to the top of the blood chamber, provide pathways for bubbles to move upward to the purge port. The inlet, outlet and gas purge tubes are threaded through, bonded to, and sealed within a rigid top-plate.

The V-Bag™, is made by welding two polyvinyl chloride films to form an expandable blood chamber with a front and back wall. A polyester screen with a pore size of 105μ is sealed between the two walls along their vertical sides as well as along the front wall at the bottom thereby forming a pouch between the screen and the front wall. The inlet tube enters the blood chamber at its top and extends diagonally to the bottom of the pouch. Blood flows from across the screen to the outlet port. The screen, once wet, allows passage of liquid but rejects most air bubbles. Bubbles in the pouch float up and are removed through the purge line.

7. Indications for use:

   The Circulatory Technology Inc. V-BAG™ with GBS® Coating is a disposable soft shell venous reservoir that accepts venous and cardiotomy blood and facilitates the removal of air bubbles during surgical procedures requiring extracorporeal support for up to six hours. When used with the Vac-Box, it can be used for Vacuum Assisted Venous Drainage (VAVD).

8. Contraindications:

   For heparin coated devices, heparin has been reported, on rare occasions, to induce thrombocytopenia. Since patients undergoing cardiopulmonary bypass are routinely systemically heparinized, and although the amount of heparin contributed by this device is very small in comparison to the typical dose given, caution should be exercised when using this device in patients with known or suspected heparin sensitivity.

9. Comparison:

   The Circulatory Technology Inc. V-BAG™ with GBS® Coating has the same device characteristics as the predicate devices, The V-Bag, Circulatory Technology, Inc., K001822.

10. Test Data:

    The Circulatory Technology Inc. V-BAG™ with GBS® Coating has been subjected to extensive safety, performance, and validations prior to release. Final testing for the systems includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications.

11. Literature Review:

    A review of literature pertaining to the safety and effectiveness has been conducted. Appropriate safeguards have been incorporated in the design of Circulatory Technology Inc. V-BAG™ with GBS® Coating.

12. Conclusions:

    The conclusion drawn from these tests is that Circulatory Technology Inc. V-BAG™ with GBS® Coating is equivalent in safety and efficacy to its predicated devices.

Edward Waddell

Edward Waddell
Director Regulatory Affairs
Gish Biomedical, Inc.

Date: Jan 25, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Gish Biomedical, Inc.
c/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071-3404

Re: K050195
V-BAG™ with GBS® Coating
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: March 1, 2005
Received: March 2, 2005

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. McInnes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K050195

Device Name: Circulatory Technology Inc. V-BAG™ with GBS® Coating

Indications for use:

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Prescription Device:

Federal Law (US) restricts this device to sale by or on the order of a physician.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050195